

## **REMARKS**

This paper is accompanied by a request for continued examination, and is being presented pursuant to 37 CFR § 1.114, and in response to the final official action dated April 27, 2010, wherein: (a) claims 11-18 and 20-27 are pending; (b) all of the pending claims have been rejected under 35 USC § 112, ¶ 2, as being indefinite; (c) claims 11-16 and 20-27 have been rejected under 35 USC § 103(a) as being obvious over Scavone (WO 02/069924 A1) and Osborne (U.S. Patent No. 6,716,441 B1); (d) claim 18 has been rejected under § 103(a) as being obvious over the combination of Scavone and Osborne in further view of Sharma (U.S. Patent No. 5,104,913); and, (e) claim 17 has been rejected under § 103(a) as being obvious over the combination of Scavone and Osborne in further view of Kelly (U.S. Patent No. 5,264,205). Reconsideration and withdrawal of the rejections are respectfully requested in view of the foregoing amendments and following remarks.

This paper is timely filed as it is accompanied by a petition under 37 CFR § 1.136(a) for an extension of time to file in the first month, and payment of the required extension fee.

### **I. Claim Status**

Claims 11-18 and 20-27 are pending in the application.

Claims 13 has been amended to clarify the carbon atom range.

Claims 26 and 27 have been amended to clarify the temperature range.

Claim 17 has been amended to correctly depend from Claim 11.

These amendments do not involve introduction of new matter. Consequently, entry of these changes are believed to be in order and is respectfully requested.

### **II. The Rejection Under 35 USC §112, ¶ 2, Is Traversed**

Claims 11-18 and 20-27 have been rejected under 35 USC § 112, ¶ 2, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

According to the action, claims 11-18 and 20-27 have been rejected because of the recitation of the following terms:

- “from about”
- “at least about”
- “less than about”

The action asserts that the terms “from about,” “at least about,” and “less than about” are not defined by the claim, and that the specification does not provide a standard for ascertaining the requisite degree. The action further asserts that one of ordinary skill in the art would not be reasonably apprised of the scope of the invention because one of skill would not be able to determine which term is in control. Still further, the action asserts that the claims lack clarity as to whether “from” or “about” controls the metes and bounds of the phrase “from about.” Similarly, the action asserts that the claims further lack clarity as to whether “at least” or “about” and “less than” or “about” control the metes and bounds of the phrases “at least about” and “less than about.” Reconsideration and withdrawal of the rejection are respectfully requested.

**A. Proper Basis for a § 112, ¶ 2 Rejection**

When examining a claim for compliance with § 112, ¶ 2, the Patent Office must consider the claim as a whole to determine whether the claim apprises a hypothetical person having ordinary skill in the art of its scope and, therefore, provides a clear warning to others as to what constitutes an infringement of the claim. *See, e.g., Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379 (Fed. Cir. 2000). Claim definiteness is not analyzed in a vacuum; instead, it is analyzed in light of the application’s complete disclosure, the teachings of the prior art, and the interpretation the hypothetical person

having ordinary skill in the pertinent art would attribute the claim at the time the invention was made. *In re Moore*, 439 F.2d 1232, 1235 (CCPA 1971). The analysis “focuses on whether those skilled in the art would understand the scope of the claim when the claim is read in light of the rest of the specification.” *Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 692 (Fed. Cir. 2001). According to the MPEP:

The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 USC § 112, first paragraph with respect to the claimed invention.

MPEP § 2173 (8<sup>th</sup> ed., Rev. 6, Sept. 2007). The MPEP also states that the meaning of every term recited in a claim should be apparent from “the prior art or from the specification and drawings at the time the application is filed.” MPEP § 2173.05(a)(I).

**B. The § 112, ¶ 2 Rejection is Moot/Traversed**

The term “from” has been omitted from claims 13, 26, and 27 to clarify the carbon atom range and temperature range. Accordingly, the § 112, ¶ 2 rejection of claims 13, 26, and 27 is moot.

Contrary to assertions in the action, neither of the remaining allegedly offending terms is indefinite in the context of its use in the application or its recitation in the claims. For example, the specification clearly states “at least about 35 degrees Celsius” to describe a sufficiently elevated temperature. *See* the Application at p. 26, lines 20-34. As another example, the specification clearly states “less than about 100 microns” to describe the average droplet diameter in the dispersed premix solution. *See* the Application at p. 26, lines 20-34. The applicant respectfully submits that the recitations in claims 11 and 15-18 are consistent with these passages in the specification. The applicant further respectfully submits that a person having ordinary skill in the art—having read the specification—would have no difficulty with measuring the temperature of the premix, or measuring the average droplet diameter in the dispersed premix solution. The applicant

also respectfully submits that a person having ordinary skill in the art—having read the specification—would have no difficulty in interpreting “at least about” or “less than about,” and concluding whether or not the recited limitation is satisfied.

According to MPEP § 2173.05, although open-ended numerical ranges should be carefully analyzed for definiteness, there is no per se rule that such ranges are indefinite:

## II. OPEN-ENDED NUMERICAL RANGES

Open-ended numerical ranges should be carefully analyzed for definiteness. For example, when an independent claim recites a composition comprising “at least 20% sodium” and a dependent claim sets forth specific amounts of nonsodium ingredients which add up to 100%, apparently to the exclusion of sodium, an ambiguity is created with regard to the “at least” limitation (unless the percentages of the nonsodium ingredients are based on the weight of the nonsodium ingredients). On the other hand, the court held that a composition claimed to have a theoretical content greater than 100% (i.e., 20-80% of A, 20-80% of B and 1-25% of C) was not indefinite simply because the claims may be read in theory to include compositions that are impossible in fact to formulate. It was observed that subject matter which cannot exist in fact can neither anticipate nor infringe a claim. *In re Krochel*, 504 F.2d 1143, 183 USPQ 610 (CCPA 1974).

MPEP § 2173.05(c)II (8<sup>th</sup> ed., Rev. 6, Sept. 2007). And in view of the disclosure present in the specification that unambiguously discloses the limitations, the applicant respectfully submits that the terms recited in the claims are sufficiently clear and definite.

The action does not articulate a *prima facie* case demonstrating that claims 11-18 and 20-27 are indefinite. Absent a *prima facie* case, and in view of the foregoing, the applicant respectfully requests reconsideration and withdrawal of the § 112, ¶ 2, rejection.

## III. The Rejections Under 35 USC §103(a) Are Traversed

Claims 11-16 and 20-27 have been rejected under 35 USC 103(a) as being unpatentable over Scavone (WO 02/069924 A1) and Osborne (U.S. Patent No. 6,716,441 B1). See the Action at pp 4-6. Furthermore, dependent claim 18 has been

rejected over the same combination of publications (i.e., Scavone and Osborne) in further view of Sharma (U.S. Patent No. 5,104,913), and dependent claim 17 has been rejected over the same combination of publications (i.e., Scavone and Osborne) in further view of Kelly (U.S. Patent No. 5,264,205). The applicant respectfully submits that Osborne cannot be combined with other art to support a § 103(a) rejection of the claims. Furthermore, the applicant respectfully submits that even if the disclosure in Osborne could qualify as prior art, then the subject matter recited in claims 11-16 and 20-27 is not obvious over the combined disclosures of the applied prior art. Accordingly, the applicant respectfully traverses the § 103(a) rejections on multiple grounds and respectfully requests reconsideration and withdrawal of the rejections. A complete response to the rejections is set forth below.

**A. Proper Basis for a § 103(a) Rejection**

The action properly describes 35 USC § 103(a). *See* the Action at p. 4. A determination that a claimed invention is obvious under § 103(a) is a legal conclusion involving four factual inquiries: (1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) secondary considerations, if any, of non-obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).

The Patent Office “has the burden under § 103 to establish a prima facie case of obviousness.” *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988); MPEP § 2142 (8<sup>th</sup> Ed., Rev. 6, Sept. 2007) (“The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness.”). The Supreme Court recently identified a number of rationales that may be used to support a conclusion of obviousness, consistent with the framework set forth in its decision in *Graham v. John Deere Co.* *See KSR Int’l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1739-40 (2007). These and other representative rationales are described at MPEP § 2143 (8<sup>th</sup> Ed., Rev. 6, Sept. 2007). Regardless of the supporting rationale, however, the Patent Office must clearly articulate facts and reasons why the claimed invention “as a whole” would have been obvious to a hypothetical

person having ordinary skill in the art at least as of the claimed invention's effective filing date. *See KSR Int'l*, 127 S.Ct. at 1741 (citing with approval *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.")); *see also* MPEP § 2143 ("The key to supporting any rejection under 35 USC § 103 is the clear articulation of reason(s) why the claimed invention would have been obvious."). The applicant respectfully submits that the Patent Office has not articulated a *prima facie* case of obviousness necessary to support its § 103(a) rejection of the pending examined claims.

Additionally, subject matter developed by another that qualifies as prior art only under 35 USC § 102(c), (f), or (g) shall not preclude patentability under § 103(a) where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person. *See* 35 USC § 103(c). The applicant respectfully submits that one of the prior art publications applied by the Patent Office to support each of its § 103(a) rejections does not qualify as prior art in view of the proscriptions set forth in § 103(c).

**B. The § 103(a) Rejections Are Traversed**

**1. Osborne (U.S. Patent No. 6,716,441 B1) Is Not Prior Art**

All of the pending claims have been rejected under § 103(a) as being obvious over a combination of publications that includes Osborne, U.S. Patent No. 6,716,441. The rejection is substantively traversed on the grounds presented below. The rejection, however, is separately traversed on the ground that Osborne does not qualify as prior art against any of the pending claims. Certain categories of prior art can be disqualified from a consideration of whether the pending claims are obvious. For example:

Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (c), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.

35 USC § 103(c)(1). Subject matter qualifies as prior art under 35 USC § 102(c)(2) if the invention was described in “a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent.”

Osborne issued April 6, 2004, from an application filed in the Patent Office under 35 USC § 111(a) on December 17, 1999. Osborne did not publish as a U.S. patent application publication. *See* 35 USC § 122(b). The current application was filed in the Patent Office February 27, 2004, and claims priority benefit under 35 USC § 120 to earlier filed applications. Osborne qualifies as presumptive prior art against the pending claims in the current application *only* under § 102(c)(2).

The current application and Osborne are owned by The Procter & Gamble Company (“P&G”). Osborne was assigned to P&G by virtue of an assignment recorded in the Patent Office at Reel/Frame 010733/0629 on April 10, 2000. The current application was assigned to P&G by virtue of an assignment recorded in the Patent Office at Reel/Frame 014735/0266 on June 16, 2004. These assignments are evidence that the subject matter disclosed in Osborne and the subject matter recited in the pending claims of the current application were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person. Consequently, Osborne does not qualify as prior art against any of the pending claims.

The § 103(a) rejection of the subject matter recited in the pending claims relies on the availability of Osborne as prior art. However, no *prima facie* case of obviousness exists because Osborne is not prior art to the subject matter recited in any of these claims. Accordingly, the applicant respectfully requests reconsideration and withdrawal of the § 103(a) rejections of the pending claims on this basis alone.

**2. The Patent Office Has Not Set Forth a Prima Facie Case of Obviousness**

The action does not clearly articulate facts and reasons why the claimed invention "as a whole" would have been obvious to a hypothetical person having ordinary skill in the art. Specifically, the action does not articulate accurate findings of fact relating to the scope and content of the prior art, and the differences between the claimed invention and the prior art. Still further, while the action appears to rationalize its conclusion of obviousness, the action does not articulate facts sufficient to support the asserted rationale. *See* MPEP § 2143. The action, therefore, does not set forth a prima facie case of obviousness. Accordingly, the applicant respectfully traverses the rejection, and requests reconsideration and withdrawal of the rejection.

Independent claim 11 recites a method comprising the steps of (a) providing a carrier system; (b) mixing a premix solution comprising niacinamide and a material selected from the group consisting of glycerin, propylene glycol, panthenol, and mixtures thereof at a temperature of at least about 35 degrees C; and, (c) milling the premix solution into the carrier system at a temperature of at least about 35 degrees C to disperse the premix solution until an average droplet diameter of the dispersed premix solution is less than about 100 microns. Dependent claims 12-16 and 20-27 recite additional features of the carrier system, premix, mixing parameters, and milling parameters.

The primary prior art reference (Scavone) discloses a method for preparing a lotion, such as an antiperspirant or deodorant composition, that contains a Vitamin B<sub>3</sub> derivative (e.g., niacinamide) and low concentrations of glycerin. In the Scavone method, an intermediate composition is prepared by mixing together a deodorant active, the Vitamin B<sub>3</sub> material, a suspending agent, and an anhydrous carrier liquid. The composition is heated to form a liquid and then glycerin is added to the heated intermediate. The resulting glycerin-containing intermediate is milled to reduce particle size. *See* Scavone at p.14, lines 1-36.

The secondary prior art reference (Osborne) discloses the effective delivery of a therapeutic skin care active to the skin via a novel release composition comprising one or more skin care actives, a release agent, and a barrier protectant, where the barrier



protectant (e.g., petrolatum) can function as a carrier and exhibit a long-lasting coating. See Osborne at the abstract; column 1, lines 64-67; and column 2, lines 57-64.

In contrast to the subject matter recited in independent claim 11, neither Scavone nor Osborne discloses mixing a premix solution that contains niacinamide and a material selected from the group consisting of glycerin, propylene glycol, panthenol, and mixtures thereof. Furthermore, neither Scavone nor Osborne discloses milling the premix solution into a carrier system as a subsequent step. Still further, the primary prior art reference (Scavone) *requires* the presence of an anhydrous carrier that is substantially free of all organic nonvolatile liquids having a C log P value greater than 7.0. This requirement is not encompassed by the subject matter recited in the pending claims. Still further, the secondary prior art reference (Osborne) does not provide any description of the potential interchangeability of petrolatum for an anhydrous liquid that is substantially free of all organic nonvolatile liquids having a C log P value greater than 7.0.

The action supports the § 103 rejection of claims 11-16 and 20-27 by the rationale that all of the features/elements recited in the rejected claims were known in the prior art, and that the ordinarily skilled artisan could have combined those known features/elements, as claimed, by known methods with no change in their respective functions to yield predictable results. But, the action does not articulate any findings that the prior art actually discloses each and every claimed element. Specifically, the action does not set forth where in the prior art there is a disclosure of the following features/elements that are recited in the rejected claims: (i) mixing a premix solution that contains niacinamide and a material selected from the group consisting of glycerin, propylene glycol, panthenol, and mixtures thereof, and (ii) milling a premix solution into a carrier system. The asserted rationale supporting the § 103 rejection does not apply, however, absent such a disclosure in the prior art. See MPEP § 2143 (A).

Scavone and Osborne, alone or in combination, do not teach or suggest all of the claim limitations of independent claim 11, therefore, a *prima facie* case of obviousness

has not been established (*see* MPEP § 2143.03). Accordingly, the rejection is respectfully traversed, and reconsideration and withdrawal of the rejection are respectfully requested.

The action also supports the § 103 rejection of claims 11-16 and 20-27 by the rationale that the skilled artisan would have been motivated to combine the prior art to achieve the claimed invention *and* that there would have been a reasonable expectation of success. *See* the Action at 5. Specifically, the action asserts that there was some teaching, suggestion, or motivation in the knowledge generally available to one of ordinary skill in the art to modify the reference or to combine reference teachings:

“One of ordinary skill in the art would have been motivated to use petrolatum as a carrier in the method of preparing a lotion by milling at ambient conditions as taught by Scavone et al. because petrolatum as per Osborne et al. is a well known effective carrier in lotions.”

The Action at p. 5.

The applicant respectfully disagrees that one skilled in the art at the time of the invention would have been motivated to modify the teachings of Scavone at all, let alone with the petrolatum carrier of Osborne, to arrive at the claimed invention. The anhydrous, liquid carrier of Scavone must allow a water soluble, skin active solid (e.g., Vitamin B<sub>3</sub>) to dissolve in sweat or other moisture on the skin after application. *See* Scavone at page 9, line 36 to page 10, line 1. If the carrier of Scavone includes a compound that forms a water-impermeable or water-inhibiting barrier around much or all of the water-soluble active solid (e.g., Vitamin B<sub>3</sub>), the rate or extent of dissolution and release of the water-soluble active solid into the sweat or other moisture on the skin is inhibited, thus efficacy is inhibited. According to Scavone, the anhydrous liquid carrier must be substantially free of organic nonvolatile liquids having a C log P value greater than 7.0 because they form the water-impermeable or water-inhibiting barrier around much or all of the water-soluble skin active solids. Scavone at page 10, lines 4-9. The negative limitation preferably applies to materials that are solid under ambient conditions but that are at least partially melted and in liquid form at or below 37 °C, or which are

otherwise in liquid form in the composition as applied topically to the skin. *See* Scavone at page 11, lines 9-12.

The applicant respectfully submits that one skilled in the art would not be motivated to modify the lotion of Scavone to arrive at the lotion of the instant invention because the lotion of the instant invention is in liquid form as applied topically to the skin:

"However, the solid and semisolid lotion compositions can be made flowable for transfer or migration of the compositions onto the skin by applying shear stress that results in deformation of the compositions. The shear stress applied at least once during wear of the absorbent article under temperature conditions of about 40 °C is typically at about  $1.0 \times 10^6$  dynes/cm<sup>2</sup>, and this shear stress can result in lotion compositions having a viscosity of from about  $1 \times 10^1$  centipoise to about  $1 \times 10^5$  centipoise. It is believed that the lotion compositions achieve the lower viscosity values under applied shear stress due to the fact that, while the compositions contain solid components, they also contain liquid materials."

The Application at p. 21, lines 10-22. Furthermore, even if one skilled in the art would have been motivated to modify the lotion of Scavone to form the lotion of the instant invention, the applicant respectfully submits that such a person would not have been motivated to combine the lotion of Scavone with the petrolatum of Osborne. Petrolatum is a semisolid and not an anhydrous liquid that is substantially free of organic nonvolatile liquids having a C log P value greater than 7.0, which is required by Scavone. The action identifies no evidence that modifying the lotion of Scavone to result in the lotion of the instant invention, as suggested by the action, would not render the lotion of Scavone unsatisfactory for its intended purpose. Where the modification to the primary prior art proposed in the action would render the primary prior art invention unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the modification proposed in the action. *See In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984); *see also*, MPEP § 2143.01(V) (8<sup>th</sup> Ed., Rev. 6, Sept. 2007).

The action notes that changing the sequence of prior art processing steps, or changing the order of mixing ingredients is *prima facie* obvious in the absence of new or unexpected results. *See* the Action at 6.

The applicant respectfully submits, however, that the pending claims recite an entirely different method than the method disclosed in Scavone because Scavone does not recite steps relating to (i) mixing a premix solution comprising niacinamide and a material selected from the group consisting of glycerin, propylene glycol, panthenol, and mixtures thereof at a temperature of at least about 35 degrees C; and, (ii) milling the premix solution into the carrier system at a temperature of at least about 35 degrees C to disperse the premix solution until an average droplet diameter of the dispersed premix solution is less than about 100 microns.

The premix step of recited in the pending claims was found by the applicant to be essential to the formation of the lotion for reliable high speed processing onto a substrate. The applicant respectfully submits, for example, that when niacinamide was milled directly into petrolatum the formation of undesirable agglomerates occurred. Further, the applicant respectfully submits that these agglomerates also occurred using the method of Scavone to form the lotion of the instant invention (e.g., mixing together niacinamide and petrolatum to form a heated liquid, adding glycerin to the heated liquid to form an intermediate, and milling the heated intermediate). Lotions containing these agglomerates were found to be unsatisfactory for their intended purpose. Application at page 26, lines 15-19. The applicant respectfully submits that where, as here, the modification to the primary prior art proposed in the action would render the primary prior art invention unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the modification proposed in the action. *See In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984); *see also*, MPEP § 2143.01(V) (8<sup>th</sup> Ed., Rev. 6, Sept. 2007).

Accordingly, the rejection of claims 11-16 and 20-27 is respectfully traversed, and reconsideration and withdrawal of the rejection are respectfully requested.

As noted above, claim 18 has been rejected under § 103(a) as being unpatentable over Scavone and Osborne, as applied to claims 11-16 and 20-27 above, and further in view of Sharma et al. *See* the Action at p 6. The applicant respectfully submits that the subject matter recited in claim 18 is not obvious over the combined disclosures of the

applied prior art. Specifically, the action asserts that the combination of Scavone and Osborne is silent on the use of an average particle size of about 2 microns, but that Sharma teaches that milling of a composition including propylene glycol and petrolatum can produce particles typically having average particle size of about 2 microns. *See the Action at 6-7.*

This rejection is premised upon the propriety of the § 103(a) rejection of claim 11, from which claims 18 depends. The rejection is substantively traversed on the same grounds that the applicant provides for traversing the rejection of independent claim 11. Dependent claim 18 recites further features of the subject matter recited in independent claim 11. Sharma, however, does not remedy the disclosure deficiencies in Scavone and Osborne relative to claim 11, as set forth above. Because, as the applicant respectfully submits, independent claim 11 is not rendered obvious by the combination of the Scavone and Osborne, dependent claim 18 *also* is not rendered obvious by that combination *even in view of* Sharma. Accordingly, the applicant respectfully traverses the rejection on this same basis, and respectfully requests reconsideration and withdrawal of the rejection on this basis alone.

The rejection is additionally traversed because claim 18 recites an average droplet diameter of the dispersed premix solution of less than about 50 microns, not less than about 2 microns, as described in Sharma.

As noted above, claim 17 has been rejected under § 103(a) as being unpatentable over Scavone and Osborne, as applied to claims 11-16 and 20-25 above, and further in view of Kelly. Specifically, the action asserts that the combination of Scavone and Osborne is silent on the milling temperature being below 50 degrees Celsius, but that Kelly teaches that milling of a composition is done at a temperature of below 50 degrees Celsius. The action further asserts that one of ordinary skill in the art would have been motivated to mill the composition at a temperature of about 50 degrees Celsius because it is known that compositions are effectively milled at this temperature. Still further, the action asserts that the determination of optimum temperature is well within the skill of the

artisan at the time of the invention and would not have required undue experimentation or have been outside the realm of knowledge generally available to the skilled artisan. *See* the Action at 7.

This rejection is premised upon the propriety of the § 103(a) rejection of claim 11, from which claims 17 depends. The rejection is substantively traversed on the same grounds that the applicant provides for traversing the rejection of independent claim 11. Dependent claim 17 recites further features of the subject matter recited in independent claim 11. Kelly, however, does not remedy the disclosure deficiencies in Scavone and Osborne relative to claim 11, as set forth above. Because, as the applicant respectfully submits, independent claim 11 is not rendered obvious by the combination of the Scavone and Osborne, dependent claim 17 *also* is not rendered obvious by that combination *even in view of* Kelly. Accordingly, the applicant respectfully traverses the rejection on this same basis, and respectfully requests reconsideration and withdrawal of the rejection on this basis alone.

In view of the foregoing, the applicant respectfully submits that the Patent Office, again, has not articulated accurate facts and reasons sufficient to demonstrate that the claimed invention as a whole would have been *prima facie* obvious to a hypothetical person having ordinary skill. Accordingly, the applicant respectfully traverses the § 103(a) rejections and respectfully submits that the claimed invention is patentable under all the criteria relevant to a determination of unobviousness. The applicant, therefore, respectfully requests reconsideration and withdrawal of the § 103(a) rejections.

*Prima facie* obviousness under § 103 is a legal conclusion—not a fact—based on underlying facts. *In re Rinehart*, 531 F.2d 1048, 1052 (CCPA 1976); *In re Kumar*, 418 F.3d 1361, 1365 (Fed. Cir. 2005) (“Determination of obviousness under 35 USC § 103 is a legal conclusion based on underlying facts.”). The foregoing response identifies facts (e.g., evidence in the form of statements in the prior art) rebutting the alleged legal conclusion that the claimed invention is *prima facie* obvious. All of these facts must be evaluated along with the facts on which the legal conclusion was originally reached—not

the legal conclusion itself. Having requested herein reconsideration of the legal conclusion set forth in the official action, the Patent Office is obligated to address all of the evidence and base its forthcoming legal conclusion(s) on such evidence, uninfluenced by its earlier conclusions. *Rinehart*, 531 F.2d at 1052.

#### **IV. Miscellaneous Remarks**

The action acknowledges the applicant's claim for priority benefit under 35 USC § 120 to earlier filed patent applications, but concludes that the applicant is not entitled to the priority benefit of the filing dates of any of those applications. *See* the Action at 2-3. The applicant does not necessarily concede that conclusion, but does not present an argument to that affect herein as the Patent Office has not articulated a prima facie case of obviousness or anticipation that otherwise requires the applicant to demonstrate its entitlement to the priority benefit it has claimed.

#### **CONCLUSION**

This response represents an earnest effort to place the present application in proper form and to distinguish the invention as claimed from the applied references. In view of the foregoing, entry of the amendments presented herein, reconsideration of this application, and allowance of the pending claims are respectfully requested.

Respectfully submitted,

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